ARC 1747C

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code section 136A.8, the Department of Public Health hereby amends Chapter 4, "Center for Congenital and Inherited Disorders," Iowa Administrative Code.

These amendments add the newborn hearing screening program, Iowa Early Hearing Detection and Intervention, to the purview of the Center for Congenital and Inherited Disorders; describe the authority of the Department to collect, test, and store newborn screening specimens and conduct follow-up and quality assurance activities; include a new rule that describes newborn screening for critical congenital heart disease; define the time frame for retention of newborn screening data; and amend a paragraph to require informed consent of the parent or guardian prior to the release of specimens for research use and to provide an effective date for the informed consent process. Paragraph 4.6(3)"a" requiring the use of a sliding fee scale by the neuromuscular and related disorders program is rescinded.

The Department has provided an effective date of January 1, 2016, for the informed consent procedure to allow for policy development prior to implementation. A procedure is also described to enable parents or guardians to indicate refusal to allow the newborn's specimen to be used for research for newborns with specimens collected prior to the effective date of the informed consent procedure.

The initial Notice of Intended Action for this rule making was published in the May 28, 2014, Iowa Administrative Bulletin as **ARC 1471C**. The Department received public comment and made changes based on public comment. A request was received from the American Heart Association along with 54 interested Iowa citizens to have the opportunity to make oral presentations on the changes made to the original Notice of Intended Action. An Amended Notice of Intended Action was published in the August 6, 2014, Iowa Administrative Bulletin as **ARC 1567C**. A public hearing was held on August 26, 2014.

Public comments addressed the informed consent for the release of residual newborn screening specimens for research purposes and suggested a later effective date for the process of obtaining informed consent. As a result of this comment, the date in paragraph 4.3(2)"e" was changed from July 1, 2015, to January 1, 2016, to provide a later effective date upon and after which informed consent for the release of residual newborn screening specimens for research purposes shall be obtained.

Other public comments requested further clarification of "other means" of newborn screening for critical congenital heart disease (CCHD) and supported the Department's efforts to ensure that all newborns are screened for CCHD. Changes were made to new subparagraph 4.3(9)"b"(3) (Item 19) to define allowable newborn screening for CCHD methodology as those methods approved by the most recently published guidelines, algorithms, and protocols as outlined by the American Academy of Pediatrics, the American College of Cardiology Foundation and the American Heart Association or subsequent guidance by those organizations.

A comment was received recommending that, due to the unknown nature of the reporting system and the burden it may place on birthing facilities, the requirement in paragraph 4.3(9)"e" regarding reporting results of newborn CCHD screening not be implemented until such time as the CCHD reporting system is developed. No change was made to paragraph 4.3(9)"e," as it is language taken directly from statute and does not affect birthing facilities until such time as a reporting system is in place.

The State Board of Health adopted these amendments on November 12, 2014.

After analysis and review of this rule making, the impact on jobs is anticipated to be minimal.

These amendments are intended to implement Iowa Code chapter 136A and Iowa Code section 135.131.

These amendments will become effective on January 14, 2015.

The following amendments are adopted.

ITEM 1. Amend rule 641—4.1(136A), introductory paragraph, as follows:

641—4.1(136A) Program overview. The center for congenital and inherited disorders within the department of public health provides administrative oversight to the following: Iowa newborn screening

program, ~~expanded maternal serum alpha-fetoprotein screening~~ Iowa maternal prenatal screening program, regional genetic consultation service, neuromuscular and related genetic disease program, ~~and~~ Iowa registry for congenital and inherited disorders, and Iowa early hearing detection and intervention program.

ITEM 2. Adopt the following **new** definitions in rule **641—4.2(136A)**:

"Critical congenital heart disease" or *"CCHD"* means the presence of one or more specific heart lesions: hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus.

"Early hearing detection and intervention program" means Iowa's newborn hearing screening and follow-up program which ensures that all newborns and toddlers with hearing loss are identified as early as possible and provided with timely and appropriate audiological, educational and medical intervention and family support.

"Newborn critical congenital heart disease (CCHD) screening" means the screening of newborns for seven targeted heart conditions (hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus) using pulse oximetry or other means to detect blood oxygen saturation levels.

ITEM 3. Amend rule **641—4.2(136A)**, definitions of "Committee," "Primary health care provider" and "Residual newborn screening specimen," as follows:

"Committee" means the ~~center for~~ congenital and inherited disorders advisory committee (CIDAC).

"Primary health care provider" means a licensed physician, physician assistant, nurse practitioner, or certified nurse midwife providing ongoing primary medical care to a patient.

"Residual newborn screening specimen" means the portion of the dried blood spot specimen that may be left over after all activities necessary for the Iowa newborn screening program are completed.

ITEM 4. Adopt the following **new** paragraph **4.3(1)"d"**:

d. For purposes of newborn screening, the department shall collect newborn screening specimens and data, test the specimens for disorders on the universal screening panel, conduct follow-up on abnormal screening results, conduct quality improvement and quality assurance activities, and store specimens for a time period determined by policies established by the CIDAC and the department.

ITEM 5. Amend subrule 4.3(2), catchwords, as follows:

4.3(2) ~~*Neonatal metabolic*~~ *Newborn blood spot screening procedure for facilities and providers.*

ITEM 6. Amend paragraph **4.3(2)"b"** as follows:

b. ~~*Waiver*~~ *Refusal of screening.* Should a parent or guardian refuse the screening, said refusal shall be documented in the infant's medical record, and the parent or guardian shall sign the refusal of screening ~~waiver~~ form. The birthing facility or attending health care provider shall submit the signed refusal of screening ~~waiver~~ form to the central laboratory within six days of the refusal. The birthing facility or attending health care provider may submit refusal forms via the courier service established for the transportation of newborn screening specimen collection forms.

ITEM 7. Amend paragraph **4.3(2)"e"** as follows:

e. ~~*Waiver*~~ *Informed consent for the release of residual specimens for research use.* The department shall establish policies and procedures, including ~~a refusal for research waiver form~~ an informed consent for release of specimens for research, to allow a parent or guardian the ability to ~~refuse~~ provide informed consent prior to the release of the newborn's residual newborn screening specimen for research purposes. The parent or guardian, birthing facility or attending health care provider shall submit the ~~signed refusal for research waiver~~ informed consent form to the central laboratory pursuant to established policy and procedure. The informed consent procedure shall apply to all specimens collected on or after January 1, 2016. For specimens collected prior to January 1, 2016, a parent or guardian may send a letter stating that the newborn's specimen is not to be released for research purposes. This letter shall include the parent's or guardian's name, the newborn's name at birth, and the newborn's date of birth. The letter of notice shall be sent to the State Hygienic Laboratory at Newborn Screening Program, State Hygienic Laboratory, 2220 S. Ankeny Blvd., Ankeny, Iowa 50023-9093.

ITEM 8. Amend paragraph **4.3(3)"b"** as follows:

b. Procedures for specimen collection for newborn blood spot screening shall be followed in accordance with 4.3(2).

ITEM 9. Amend paragraph **4.3(4)"e"** as follows:

e. Notification. The birthing facility shall report the newborn screening results to the health care provider who has undertaken ongoing primary pediatric care of the infant.

ITEM 10. Amend paragraph **4.3(6)"b"** as follows:

b. The follow-up programs shall submit a written annual report of the previous calendar year by July 1 of each year. The report shall include:

(1) No change.

(2) ~~Method and timing of referrals made to the follow-up programs~~ Number of confirmed cases receiving follow-up,

~~(3) Each individual's age at confirmation of disorder,~~

~~(4) Each individual's age when treatment began,~~

~~(5) Type of treatment for each individual with a disorder, and~~

~~(6)~~ (3) A written summary of educational and follow-up activities.

ITEM 11. Amend subrule 4.3(7), introductory paragraph, as follows:

4.3(7) *Sharing of information and confidentiality.* Reports, records, and other information collected by or provided to the Iowa newborn screening program relating to an infant's newborn screening results and follow-up information are confidential records pursuant to Iowa Code ~~section~~ sections 22.7 and 136A.7. INSP data may be retained indefinitely.

ITEM 12. Amend subparagraph **4.3(7)"b"(1)** as follows:

(1) The parent or guardian of an infant or child or the adult individual for whom the report is made.

ITEM 13. Amend paragraph **4.3(8)"a,"** introductory paragraph, as follows:

a. A newborn screening specimen collection form consists of a filter paper containing the dried blood spots (DBS) specimen and the attached requisition that contains information about the infant and birthing facility or drawing laboratory. The DBS specimen can be separated from the information contained in the requisition form. The INSP is the custodian of the specimens and related data for purposes of newborn screening, quality improvement and quality assurance activities.

ITEM 14. Reletter paragraph **4.3(8)"b"** as **4.3(8)"c."**

ITEM 15. Adopt the following **new** paragraph **4.3(8)"b"**:

b. The program shall not release a residual newborn screening specimen except to the following persons and entities:

(1) The parent or guardian of the infant or the individual adult upon whom the screening was performed.

(2) A health care provider acting on behalf of the patient.

(3) A medical examiner authorized to conduct an autopsy on a child or an investigation into the death of a child.

(4) A researcher for research purposes, under the terms and conditions provided in this rule.

(5) The newborn screening program, for operations as provided in this rule.

ITEM 16. Amend relettered paragraph **4.3(8)"c"** as follows:

c. Research ~~use~~. A residual newborn screening specimen may be released for research purposes only if written consent has been received from a parent or guardian of the child, or the individual adult upon whom the screening was performed, and each of the following conditions is satisfied:

(1) Investigators shall submit proposals to use residual ~~DBS~~ newborn screening specimens to the center. Any ~~intent to utilize information associated with~~ intended use of the requested specimens as part of the research study must be clearly delineated in the proposal.

(2) Before research can commence, proposals shall be approved by the researcher's institutional review board, the congenital and inherited disorders advisory committee, and the department.

~~(3) Personally identifiable residual specimens or records shall not be disclosed without documentation of informed parental consent obtained by the researcher.~~

~~(4)~~ (3) Research on anonymized or identifiable residual newborn screening specimens shall be allowed only in instances where research would further: newborn screening activities; the health of an infant or child for whom no other specimens are available or readily attainable; ~~or~~ general medical knowledge for existing public health surveillance activities; public health purposes; or medical knowledge to advance the public health.

ITEM 17. Adopt the following **new** paragraphs **4.3(8)"d"** and **"e"**:

d. Newborn screening program operations. Residual newborn screening specimens may be used for activities, testing, and procedures directly related to the operation of the newborn screening program, including confirmatory testing, laboratory quality control assurance and improvement, calibration of equipment, evaluation and improvement of the accuracy of newborn screening tests, and validation of equipment and screening methods, and the use of linked specimens in feasibility studies approved by the Congenital and Inherited Disorders Advisory Committee for the purpose of incorporating new tests or evaluating new test methodologies.

e. Prohibited uses. A residual newborn screening specimen shall not be released to any person or entity for commercial purposes or law enforcement purposes or to establish a database for forensic identification.

ITEM 18. Renumber subrules **4.3(9)** and **4.3(10)** as **4.3(10)** and **4.3(11)**.

ITEM 19. Adopt the following **new** subrule 4.3(9):

4.3(9) *Newborn screening for critical congenital heart disease.* All newborns and infants born in Iowa shall receive newborn screening for CCHD, by pulse oximetry or other means in accordance with subparagraph 4.3(9)*"b"*(3). The purpose of newborn screening for CCHD is to identify newborns with structural heart defects usually associated with hypoxia in the newborn period which could have significant morbidity or mortality early in life with the closing of the ductus arteriosus or other physiological changes early in life.

a. Newborn CCHD screening procedure for providers and facilities.

(1) Educating parent or guardian. Before newborn screening for CCHD on an infant is conducted, a parent or guardian shall be informed of the type of screening, how it is performed, the nature of the disorders for which the infant is being screened, and the follow-up procedure for an abnormal screen result.

(2) Refusal. Should a parent or guardian refuse the screening, said refusal shall be documented in the infant's medical record, and the parent or guardian shall sign the refusal of screening form. The birthing facility or attending health care provider shall submit the signed refusal form to the central laboratory within six days of the refusal. The birthing facility or attending health care provider may submit refusal forms via the courier service established for the transportation of newborn screening specimen collection forms.

b. Newborn CCHD screening for newborns in low-risk or intermediate nurseries or out-of-hospital births.

(1) Screening should not begin until the newborn is at least 24 hours of age, or as late as possible if earlier discharge is planned, and should be completed on the second day of life.

(2) Screening shall be conducted using pulse oximeters or other means in accordance with subparagraph 4.3(9)*"b"*(3). Pulse oximeters shall:

1. Be motion tolerant;
2. Report functional oxygen saturation;
3. Be validated in low-perfusion conditions;
4. Be cleared by the Food and Drug Administration (FDA) for use on newborns; and
5. Have a 2 percent root-mean-square accuracy.

Disposable or reusable probes may be used. Reusable probes must be appropriately cleaned between uses according to manufacturer's instructions.

(3) Newborn CCHD screening shall be conducted by pulse oximetry or other means in accordance with the most recently published guidelines, algorithms, and protocols as outlined by the American Academy of Pediatrics, the American College of Cardiology Foundation and the American Heart Association, or subsequent guidance by the organizations listed in this subparagraph. Materials are available on the CCID Web page at http://idph.state.ia.us/genetics/newborn_screening.asp.

c. Newborn CCHD screening for high-risk newborns in neonatal intensive care settings (NICU). Until such time that an evidence-based protocol for CCHD screening in infants discharged from the NICU is available, the attending health care provider shall conduct a comprehensive examination of the newborn to screen the infant for CCHD prior to discharge.

d. Primary health care provider responsibility. The health care provider shall ensure that infants under the provider's care are screened.

e. Reporting results of newborn CCHD screening. At such time as the CCHD reporting system is implemented, results of newborn CCHD screening shall be reported in a manner consistent with other newborn screening (formerly referenced as metabolic screening) reporting.

ITEM 20. Amend renumbered subrule 4.3(10) as follows:

4.3(10) *INSP ~~fee determination~~ and IMPSP fees.*

a. The department shall annually review and determine the fee to be charged for all activities associated with the INSP and the IMPSP. The review and fee determination shall be completed at least one month prior to the beginning of the fiscal year. The newborn screening fee is $122.

b. The department shall include as part of ~~this~~ the INSP fee an amount determined by the committee and department to fund the provision of special medical formula and foods for eligible individuals with inherited diseases of amino acids and organic acids who are identified through the ~~program~~ programs.

c. Funds collected through newborn screening fees shall be used for newborn screening program activities only.

d. Funds collected through maternal prenatal screening fees shall be used for maternal prenatal screening activities only.

e. In order to support newborn and maternal prenatal screening activities, the department shall authorize the expenditure and exchange of newborn screening and maternal prenatal screening funds between the SHL (as designated fiscal agent) and the department.

f. Upon department approval of proposed budgets, a portion of INSP and IMPSP fees shall be distributed to the department to support the percent of effort of the executive officer of the center for congenital and inherited disorders (CCID).

ITEM 21. Amend subrule 4.6(3) as follows:

4.6(3) ~~*Patient fees.*~~

~~*a.* A sliding fee scale for specialty genetic provider services shall be established for patients attending the outreach clinics. The parameters for the sliding fee scale shall be based on federally established percent of poverty guidelines and updated annually.~~

~~*b.* Families/clients seen in neuromuscular outreach clinics shall have bills submitted to third-party payers where applicable. Families/clients shall be billed on a sliding fee scale after third-party payment is received. Payments received from receipts of service based on the sliding fee scale or from the third-party payers shall be used only to support the neuromuscular outreach clinics.~~

~~*c.*~~ The University of Iowa Hospitals and Clinics under the control of the state board of regents shall not receive indirect costs from state funds appropriated for this program.

ITEM 22. Adopt the following **new** rule 641—4.8(135):

641—4.8(135) Iowa's early hearing detection and intervention program. The goal of universal hearing screening of all newborns and infants in Iowa is the early detection of hearing loss to allow children and their families the earliest possible opportunity to obtain appropriate early intervention services. All newborns and infants born in Iowa, except those born with a condition that is incompatible

with life, shall be screened for hearing loss. Early hearing detection and intervention programming and services will be provided pursuant to 641—Chapter 3.

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